

EXHIBIT “A”

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION))))	MDL NO. 2272 MASTER LONG FORM COMPLAINT AND JURY DEMAND
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INTRODUCTION

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint¹ against Defendants Zimmer, Inc., Zimmer Holdings, Inc., and Zimmer Orthopaedic Surgical Products, Inc. (alternatively referred to as “Defendants”). This Master Long Form Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding. Plaintiffs seek compensatory and punitive damages, monetary restitution, equitable relief, and all other available remedies as a result of injuries incurred by Defendants’ defective products. Plaintiffs make the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys’ investigative efforts, regarding the Zimmer NexGen® Flex Knee system.

This Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Master Complaint and the necessary causes of action herein through use of a separate short form complaint. Any separate facts and additional claims of individual plaintiffs are set forth in those actions filed by the respective plaintiffs. This Master

¹ Pursuant to this Court’s order of December 19, 2011. (Document No. 186)

1. The human knee is a miracle of nature that supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis among all such joints.

3. Despite the safety and efficacy success related to earlier knee replacement models, Zimmer began to tinker with the original design in an effort to replicate the total flexion of the natural knee.

5. Nevertheless, with a series of new introductions to the knee replacement market, Zimmer unveiled the Zimmer NexGen® Flex Knee system and procedures,

promoting them on the basis of “enhanced” capabilities, “minimally invasive” procedures, and gender specific designs, promising consumers, doctors and patients alike, more movement, shorter hospital stays and better fit than the existing, well functioning and reliable models.

6. In reality however, these enhanced replacement knees did not deliver on any of these promises. Worse, the “flex” design resulted in significantly higher failure rates than their standard knee counterparts. As a result, thousands of knee replacement patients have had more expensive, more dangerous and less effective revision surgery.

7. The specific medical devices at issue in this Master Long Form Complaint are as follows:

A. The NexGen® Complete Knee Solution Legacy® Posterior Stabilized-Flex (LPS-Flex) Femoral Components (LPS-Flex);

B. The NexGen® Complete Knee Solution Cruciate Retaining-Flex Femoral Components (CR-Flex);

C. The NexGen® Complete Knee Solution *Gender Solutions*™ Female LPS-Flex (GSF LPS-Flex);

D. The NexGen® Complete Knee Solution CR-Flex *Gender Solutions*™ Female CR-Flex (GSF CR-Flex); and

E. All NexGen® MIS Total Knee Procedure Stemmed Tibial Components (collectively the “Zimmer Devices” or “Zimmer NexGen® Flex Knee system” or Zimmer NexGen® Flex Knee family”).

8. The claims in this Master Long Form Complaint focus on two members of the Zimmer NexGen Knee family of replacement knee joints: 1) the so-called “Flex” or

“High Flex” knees; and 2) the MIS Stemmed Tibial Components. Both designs are defective and failed, resulting in harm to the plaintiffs within this MDL.

9. Zimmer first introduced its Zimmer NexGen Complete Knee Solutions system in 1995. Zimmer’s original design, like the vast majority of other products on the market at the time, offered a device promising standard flexion up to one-hundred-twenty degrees (120°). In an effort to expand its market share, however, Zimmer began to tinker with its knee design to create a device providing flexion up to one-hundred fifty-five degrees (155°) – the amount of relative flexion available in an anatomical human knee. By 1999 Zimmer was ready to take its product to market.

10. Specifically, in 1999, Zimmer received approval for the high-flex version (the LPS-Flex) from the Food and Drug Administration (“FDA”) under the “510k” protocol. The basis for FDA approval was substantial similarity to a prior device, resulting in very limited, if any, testing of the product.

11. Over the next decade, Zimmer continued to expand its high-flex product line under the auspices the high-flex product line would provide patients who were “expecting to maintain an active lifestyle” a more life-like knee. Zimmer aggressively marketed its high-flex product line and became the dominant player in the so-called high-flex market.

12. By 2010, the efficacy and safety of Zimmer’s high flex knee family became the subject of much doubt within the peer reviewed medical literature.

13. By June of 2010, Zimmer’s high flex knees were called into question in a New York Times expose story, concerning Zimmer’s abandonment and criticism of its

former high paid consultant who publicly criticized some high flex knee design at the American Association of Orthopedic Surgeon annual conference held earlier that year.

14. Just a short time later, The New York Times story and Zimmer's approach to the NexGen knee family became the subject of a Senate investigation.

15. Like the failed high-flex components, the other component at issue within this litigation within the Zimmer NexGen® Flex Knee family of replacement knee products involves its failed MIS Stemmed Tibial components and corresponding "Minimally Invasive Surgical® Procedure ("MIS").

16. In March 2005, Zimmer received 510(k) FDA approval for the NexGen MIS Tibial components that are part of the NexGen system. The low profile design of this tibial component was developed and manufactured by Zimmer with the goal of allowing for implantation and assembly in minimally invasive knee replacement surgeries.

17. In September of 2010, the FDA recalled over 68,000 MIS Stemmed Tibial components citing alarming failure rates. The MIS Stem and its corresponding MIS surgical procedure, was designed to be assembled within the patient thereby allowing for minimally invasive surgery technique (i.e., a much smaller incision). The NexGen MIS Tibial component is marketed and promoted as compatible with the LPS-Flex and CR-Flex femoral components and they are often used together.

18. Plaintiffs allege that the NexGen high-flex knee implants are defective and as a result has caused unnecessary injury. Specifically, the high-flex device has a higher failure rate than the standard flex devices and the purported benefit of added flexion simply does not exist. The high-flex devices are prematurely failing at a significant rate

causing patients to undergo additional revision surgeries. These high-flex implants offer no clinical benefit over the standard flex implants that compensates in whole or part for the increased risk.

JURISDICTION AND VENUE

19. This court has subject matter jurisdiction pursuant to 28 United States Code §1332 as to the claims of the respective Plaintiffs.

20. The amount in controversy alleged by each of the respective individual Plaintiffs will exceed seventy-five thousand dollars (\$75,000.00).

PLAINTIFFS

21. This Master Long Form Complaint (“Master Complaint”) is filed in accordance with the December 19, 2011 Order of the Court. It is filed on behalf of all Individual Plaintiffs (collectively “Plaintiffs”) whose claims are subsumed within MDL No. 2272. Plaintiffs in these individual actions have suffered personal injuries as a result of the premature failure of their Zimmer Device. In addition, and where applicable, this Master Complaint is also filed on behalf of Plaintiffs’ spouses, children, parents, decedents, wards and/or heirs and/or decedent(s), all as represented by Plaintiffs’ counsel.

22. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants’ conduct and misconduct as described herein and in connection with, *inter alia*, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of their respective Zimmer Device.

DEFENDANTS

23. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

24. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

25. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

26. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer Devices. Defendants' products, including the Zimmer NexGen Flex Knees and MIS Stemmed Tibial Components, are sold throughout the world.

ANATOMY OF THE KNEE

27. From a lay perspective, the knee is a hinge joint where the ends of the thigh bone and the shin bone move principally in one plane like a hinge. However, the actual function of this anatomy is much more complex, as the bones are not directly attached to each other but are held together by rope-like ligaments. Movement is created by the action of muscles and tendons. The joint hinge bears weight directly on its principal articulating surfaces which are made of specialized cartilage

28. The knee is composed of three functional bones: the femur (thighbone), tibia (shinbone) and patella (kneecap). The femur is the longest and strongest bone in the body. The distal end (the lower end farthest from the center of the body) forms the upper part of the knee. This distal end has double rounded knob-like projections (the

“condyles”) with a groove in between. One condyle is on the medial (inside) of the knee, and the other on the lateral (outside) of the knee. These rounded condyles articulate (move) along the top of the tibia while the back of the patella (kneecap) moves along the groove between the condyles.

29. The femur and the tibia meet to form a pivotal hinge joint, permitting flexion (decrease of the joint angle) and extension (increase of the joint angle or straightening) of the leg as well as slight medial and lateral rotation.

30. The knee joint is protected in front by the patella (kneecap). The patella is a mostly flat, oval shaped, sesamoid bone tapered toward the distal end. Sesamoid means the bone is contained within a tendon in this case, the patellar tendon. The posterior or back side, of the patella slides between the condyles of the femur and articulates with the femur.

31. The joint is cushioned by articular cartilage that covers the ends of the tibia and femur as well as the underside of the patella. The articular cartilage is linked to the underlying bone by a complex geometric interlocking system, much like jigsaw puzzle pieces. Bone and cartilage are not connected in any way other than a mechanical connection, and are anatomically separate, with separate systems for growth, nutrition and regeneration.

32. Arthritis develops when the cartilage surface wears away creating increased pressure on the bone and therefore pain. Damage to the surface causes the cartilage to lose its firmness and increase wear. Damage is repaired by fibrous tissue which does not have the same properties as the original tissue. “Arth” means joint. The

suffix “osis” means damage. The suffix “itis” means inflammation. In osteo-arthritis, decreased elasticity and reduction in load bearing capability occurs.

33. Two other parts of the articulating joint are the menisci (“meniscus” singular).

34. The lateral meniscus and medial meniscus are pads of cartilage that further cushion the joint, acting as shock absorbers, spreading the impact of motion across the joint surfaces.

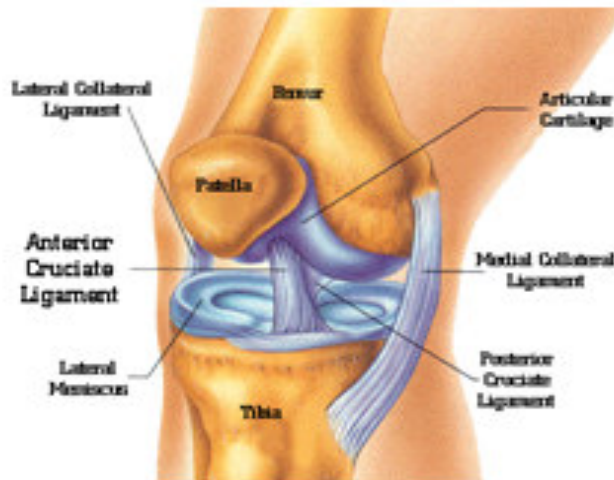
35. Ligaments stabilize the knee. The medial collateral ligament (MCL) and lateral collateral ligament (LCL) are known as the extracapsular ligaments and run on the sides of the knee. Their role is essentially to hold the femur and tibia together and resist side to side motion.

36. The anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL) are known as intra-articular ligaments and likewise hold the femur and tibia together, and resist forward and backward sliding of the femur over the tibia.

37. The main motions of the knee joint are flexion (bending) and extension (straightening), with limited medial and lateral rotation. The main muscles responsible for extension are the quadriceps, which are also the most important muscle in stabilizing the knee joint. Flexion is produced by group of muscles known as the hamstring muscles.

38. There are two articulations or points where the bones make contact: femur and tibia; and femur and patella.

Basic Knee Anatomy



39. The principal movements of the knee joint are flexion (which is bending the knee), and extension (which is straightening the knee). Typically, a healthy knee has the potential to bend to about 155 to 160 degrees. One limiting factor on flexion is the girth of the leg, so that the knee may not reach 155 degrees even though it is anatomically able to do so because the soft tissues of the thigh and calf hit each other. The healthy knee can typically extend just beyond 0 degrees.

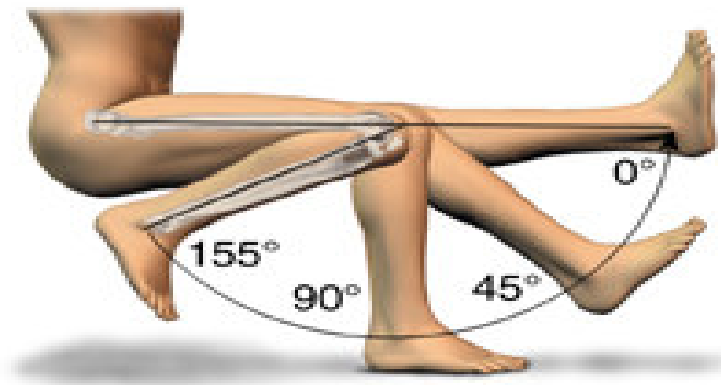
40. Most normal movements of everyday life such as walking, climbing and descending stairs, getting out of a chair, getting in and out of a car, or stooping generally require only up to 90 degrees of flexion. A modestly active person needs only about 95 degrees of flexion to engage in normal activities of daily living.

41. Infrequently, activities of daily living require up to 120 degrees of flexion, for example, getting up off the floor, or getting out of a seat where the hip is lower than the knee when seated.

42. Some infrequent activities of daily life require flexion beyond 120

degrees. For example, in some instances climbing stairs requires between 75-140 degrees, sitting in a chair and standing up again may require between 90-130 degrees, and squatting (e.g. while gardening) requires between 130-150 degrees.

Flexion and Extension

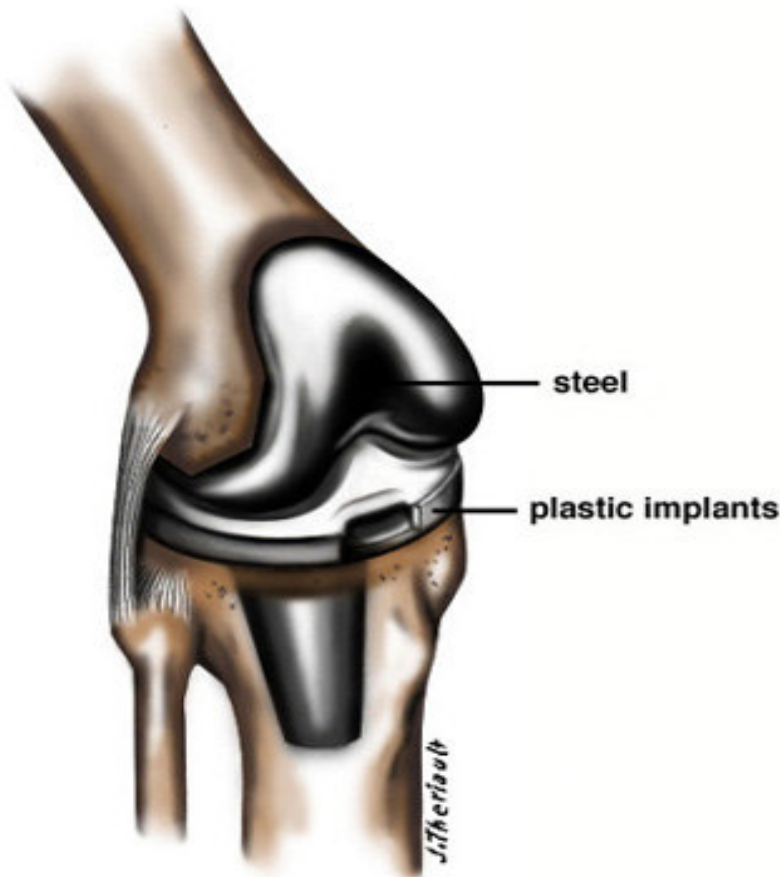


THE TOTAL KNEE REPLACEMENT PROCEDURE

43. Total knee arthroplasty (“TKA”), also called total knee replacement (“TKR”), is a commonly performed medical procedure. The surgery is designed to help relieve pain and improve joint function, generally in people with severe knee degeneration due to arthritis or trauma.

44. Knee replacement is the process of replacing the joint surfaces with artificial materials. The replacement is not nearly as good as the original but it redistributes weight and takes away the tissue causing inflammation and thus reduces pain. Replacement requires a mechanical connection between the bones and the implant components, but this bonding is never as good as the natural bonding of cartilage to bone.

TOTAL KNEE REPLACEMENT



45. A total knee arthroplasty is a misnomer, in that it is not truly a total knee replacement, but rather the resurfacing of damaged articular cartilage and bone surfaces. The main goals of the procedure are: (1) to relieve pain caused by arthritis, (2) to restore range of motion, or the degrees of knee flexion and extension, and (3) to correct any varus and valgus misalignment.

46. A total knee replacement is usually considered when disease or injury cause substantial damage to the surface of either bone or the underside of the patella.

47. The TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the femur and tibia are removed or reduced as is often the underside of the patella.

48. In total knee replacement surgery, the surface of the femur is replaced with a contoured metal component designed to fit the curve of the bone. The surface of the tibia is typically replaced with a flat metal component and a smooth plastic component that serves as a replacement for cartilage. The undersurface of the patella may also be replaced with an implant made of plastic, or a combination of metal and plastic.

49. Globally, hundreds of thousands of knee replacement procedures are performed each year, with 500,000 performed in the United States alone.

50. Ordinarily, most total knee replacements are successful up to ten years.

HISTORY OF ZIMMER AND ZIMMER NEXGEN

FAMILY OF FLEX KNEES

51. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopedic reconstructive, spinal and trauma devices, dental implants, and related orthopedic surgical products.

52. In 1927, Justin Zimmer, a national sales manager for Depuy, an orthopedic splint manufacturer, broke away and started Zimmer Manufacturing Company. Originally a company that manufactured aluminum orthopedic braces, it quickly expanded into the surgical implant business. Today, Zimmer designs, develops, manufactures and markets orthopedic implants as well as fracture products and surgical tools.

53. In 1995, Zimmer introduced its Next Generation (NexGen) Complete Knee Solution system, with various component configurations as well as surgical guides

and tools. Designed largely by John Insall, the system received FDA 510(k) clearance, demonstrating that the device was “substantially equivalent” to predicate devices previously cleared by the FDA.

54. The NexGen TKR was an integrated system combining a femoral component, a tibial component, a plastic articulating surface and a plastic replacement for the posterior surface of the patella. The surgeon had the option to save or remove the posterior cruciate ligament.

55. With the NexGen CR (Cruciate Retaining) implant, the PCL is preserved. In the LPS (Legacy Posterior Stabilized) version the posterior cruciate ligament is sacrificed.

56. The LPS implant includes a raised surface with an internal post on the tibial component that fits into a special notch on the femoral component. The post and notch work together to perform the function of the PCL: preventing the tibia from moving too far backward.

57. The basic system was very successful with a low revision rate. The system was able to achieve flexion up to between 120 and 130 degrees, depending on the patient.

58. Zimmer became the largest US manufacturer of knee replacement devices.

59. Knee replacement is Zimmer’s largest single line of business, with sales from knees alone exceeding \$1.7 billion in 2010, amounting to 42% of company revenue.

60. Despite the success of the NexGen and other Zimmer products, the knee replacement manufacturing industry remained highly competitive with at least 4 other major manufacturers.

61. While the standard NexGen CR (Cruciate Retaining) and NexGen LPS (Legacy Posterior Stabilized or cruciate sacrificing) produced excellent results and sales, the push to increase market share or expand the market to younger more active patients caused sellers to design implants that could arguably provide more function or were more attractive to the consumers, whether the consumer was a patient, a hospital, a health system or a surgeon.

62. The first step in that direction was the NexGen LPS Flex Fixed-Bearing Knee which got FDA 510k approval in 1999 and was introduced in 2001. The LPS-Flex was designed to allow for a maximum flexion of 155 degrees.

63. The NexGen CR Flex followed in 2003, also allowed up to 155 degrees of flexion.

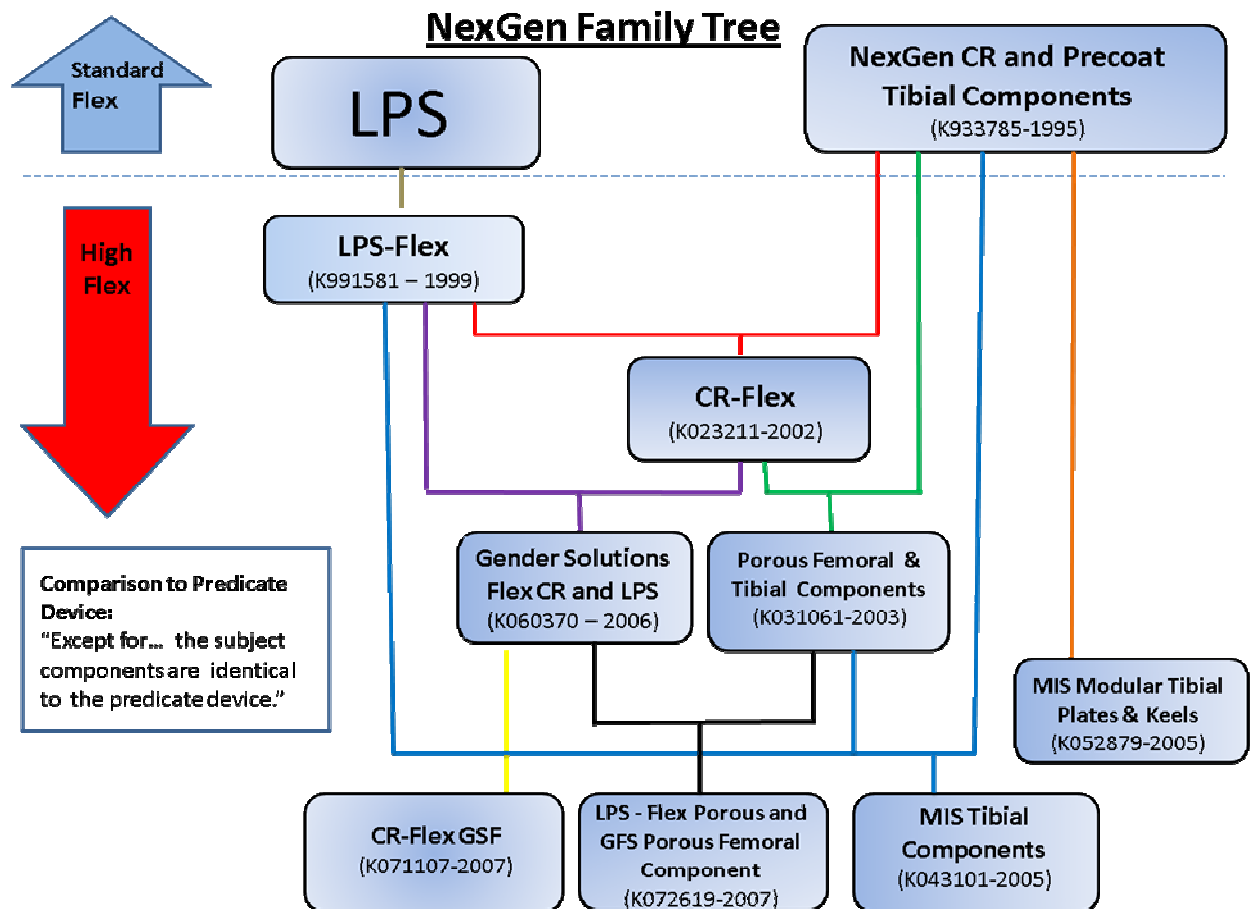
64. In 2004, Zimmer launched its Minimally Invasive Solutions (MIS) Quad-Sparing TKR Procedure. Whereas traditional TKR incisions are 8-12 inches, Zimmer's MIS incision is 3-5 inches and avoids cutting a portion of the quadriceps muscles and tendon. The stated goals were less blood loss, less pain, a shorter hospital stay, and shorter rehabilitation. On the negative side, a smaller opening limited the surgeon's view of the operative field, and required some specialized and smaller instruments and components.

65. In 2006, Zimmer launched Gender Solutions, a femoral component designed specifically for women. Differences between traditional and Gender Solutions Female (GSF) implants include a thinner profile, contoured shape, and a difference angle between the pelvis and the knee to more mimic the general anatomic differences between the female and male knee (other than size).

REGULATORY HISTORY OF ZIMMER NEXGEN KNEES

66. In 1995 Zimmer received approval from the U.S. Food and Drug Administration (“FDA”) for its NexGen Complete Knee Solution Legacy LPS Knee system as well as for its NexGen CR Knee. These designs would become the predicate devices for the “high-flex” designs that were to be introduced by Zimmer over the next decade and a half.

67. The Zimmer NexGen Complete Knee system and component parts are all interrelated and predicated upon the same design, and may be graphically summarized as follows:



68. The interrelationship of the Zimmer NexGen Knee System: LPS-Flex, CR-Flex, GSF LPS-Flex, GSF CR-Flex and MIS Tibial Components is admitted within Zimmer submissions to the FDA and was the underlying commonality that formed this MDL. Indeed, on August 8, 2011, in ordering transfer of more than forty-five (45) related actions to the Northern District of Illinois before the Hon. Rebecca R. Pallmeyer, the Judicial Panel on Multidistrict Litigation (“JPML”) noted that “[p]laintiffs reference, for example, certain 510(k) submissions that appear to reflect significant similarities among the subject femoral components, a surgical techniques brochure containing largely identical language describing the designs of the LPS-Flex and CR-Femoral components, and a Zimmer marketing pamphlet covering both the CR-Flex Gender Solutions and LPS-Flex Gender Solutions components.”

69. Zimmer’s stated design rationale for the Zimmer NexGen Flex Knee includes the statement that “[b]oth CR-Flex and LPS-Flex knees are designed to safely accommodate flexion of up to 155°. Moreover as postoperative flexion can be somewhat unpredictable, the CR-Flex and LPS-Flex knees have been designed for use *in all patients, including those who do not appear to have the need to achieve higher flexion.*” (Emphasis supplied).

70. Zimmer further states that common design issues to both the CR-Flex and LPS-Flex “relate to contact area between the femoral component condyles and the tibial articular surface during deep flexion, stresses on the extensor mechanism during deep flexion, patellar tracking, sizing to facilitate balancing of the flexion and extension gaps, and anterior lift-off of the tibial articular surface..”

71. Zimmer also notes that with respect to the CR-Flex and LPS-Flex, “[i]nterchangeability among the components allows the surgeon to switch from the cruciate retaining design to the posterior stabilized design intraoperatively.”

A. 510(k) approval of LPS-Flex Knee

72. Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is substantial equivalent to a device already approved for marketing.

73. The Legacy Posterior Stabilized Flex Knee (LPS-Flex) was marketed by Zimmer as “intended for patients who have adequate bone stock and whose ligaments provide moderate joint stability or for when the posterior cruciate ligament has been cut or removed.”

74. In July 1999, Zimmer received FDA 510(k) approval of its first NexGen Flex knee, the Complete Knee Solution Legacy Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components, commonly known as the LPS-Flex Fixed Bearing Knee.

75. Zimmer’s 510(k) Summary of Safety and Effectiveness submitted to the FDA in May 1999 seeking approval for the LPS-Flex Fixed Bearing Knee, states the predicate device was the NexGen Complete Knee Solution Legacy LPS Knee.

76. Zimmer’s 510(k) Summary of Safety and Effectiveness further claimed that the LPS-Flex Fixed Bearing Knee was similar to the predicate device in design, materials and performance, and identical to the predicate device sterility, biocompatibility

and pyrogenicity noting, “[e]ven though the LPS-Flex increases the maximum active flexion angle to 155 degrees, the design has maintained the conformity necessary to minimize or eliminate any new movement mechanisms that could affect wear.”

77. The LPS-Flex Fixed Bearing Knee received approval in July 1999 at which time the FDA determined it was “Substantially Equivalent” to the predicate device.

B. 510(k) approval of CR-Flex Femoral Components

78. Like the LPS-Flex, the Cruciate Retaining Flex Knee (CR-Flex) was marketed by Zimmer as “intended for patients who have good bone stock and whose ligaments provide adequate joint stability.”

79. When Zimmer approached the FDA for 510(k) approval for the CR-Flex device, it claimed that the device was substantially similar to a sister device in the self-named “Zimmer Flex-Series.”

80. In Zimmer’s 510(k) submission for the NexGen CR-Flex Zimmer listed two predicate devices: 1) NexGen LPS-Flex and NexGen CR. Zimmer’s own description of the comparison to the predicate devices states “except for modifications to allow flexion to 155 degrees, CR-Flex femoral components are *identical* to the predicate device. The modifications do not change the intended use or the fundamental scientific technology the device is packaged and sterilized using the same materials and processes.”

81. In October 2002, Zimmer received FDA 510(k) approval of its NexGen Complete Knee Solution Cruciate-Retaining (CR)-Flex Femoral Components at which time the FDA determined it was “Substantially Equivalent” to the predicate device.

C. 510(k) approval of Gender Solutions Female (GSF) LPS-Flex and CR-Flex Knees

82. In February 2006 Zimmer submitted one 510(k) application to the FDA for both the LPS-Flex and CR-Flex NexGen Gender Solutions Female “GSF” implants, which are also described as part of the “Zimmer Flex Series” The predicate devices were listed as the NexGen LPS-Flex and the CR-Flex and in its comparison to the predicate devices Zimmer states “Except for modifications to address specific anatomic features typical of a female patient, these components are *identical* to their respective predicate device. The device is packaged and sterilized using the same materials and processes.”

83. Zimmer’s February 2006 510(k) Summary of Safety and Effectiveness further noted that the “NexGen Knee GSF Femoral Components included both LPS-Flex GSF and CR-Flex GSF versions and are part of the Zimmer-Flex series of semi-constrained, nonlinked, condylar knee prostheses that are designed to have a maximum active flexion of 155 degrees.”

84. The NexGen Knee Gender Solutions Female (GSF) Femoral Components received approval in April 2006 at which time the FDA determined it was “Substantially Equivalent” to the predicate device.

D. 510(k) approval of MIS Tibial Components

85. The Zimmer NexGen Knee also uses a stemmed tibial component that is designed to be assembled within the patient thereby allowing for minimally invasive surgery techniques.

86. In March 2005, Zimmer received 510(k) FDA approval for the NexGen Complete Knee Solution MIS Tibial Components. The MIS Tibial Components are part of the NexGen system of semi constrained, non-linked, condylar knee prostheses.

87. Zimmer's 510(k) Summary of Safety and Effectiveness submitted to the FDA in November 2004 seeking approval for the NexGen Complete Knee Solution MIS Tibial Components noted that the "NexGen Complete Knee Solution MIS Tibial Components are part of the NexGen system of semi constrained, non-linked, condylar knee prostheses." The application relied upon both the LPS-Flex and the CR-Flex as the prior approved devices that share substantial equivalence.

88. The low profile design of this tibial component was developed and manufactured by Zimmer to allow for implantation and assembly in Minimally Invasive Surgical procedures ("MIS"). In a standard knee replacement surgery the incision is roughly eight inches. Conversely, a MIS surgery only requires a four to five inch incision. The theory behind the MIS surgical procedure is that the reduced incision leads to quicker healing and recovery times. Unfortunately, the theory did not play out in practice, and ultimately resulted in a more difficult procedure prone to increased failure rates.

89. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer Devices.

90. In seeking approval for the sale of the Zimmer Devices Defendants represented that each of the devices was substantially equivalent to a previously approved

or predicate device and therefore could receive premarket approval under Section 510(k) of the FDA.

91. By claiming substantial equivalence, Defendants knew the Zimmer Devices were subject to far less testing and scrutiny.

ZIMMER MARKETING OF NEXGEN KNEES

92. With the introduction of the Insall knee described above and other basic knee designs, the market became crowded with knee prostheses that could reliably eliminate pain and restore the ability to perform most daily functions with a low failure rate.

93. The only ways to increase market share was to either expand the patient base of those who receive implants (for example, younger more active patients) or offer TKR with alleged enhancements such as more function, shorter recovery times or prostheses designed to gender specifications.

94. Called in some publications “premium knees”, the new designs were more expensive but at the same time more attractive to many patients and surgeons. Zimmer took the lead in this area with 3 different enhancements. The basic NexGen LPS and CR knees were redesigned so they had the potential to flex a full 155 degrees.

95. The minimally invasive surgery, or MIS (Minimally Invasive Solutions), promised a quicker exit from the hospital and quicker recovery.

96. The “Gender Solutions” knee, all of which were flex knees, were redesigns of the standard CR and LPS, but shaped slightly different to mimic the typical anatomical differences between a male and female knee.

97. Patients were promised that they could recover faster, and engage in more active lifestyles.

98. Women, who were roughly 2/3 of the knee implant market, were told they could get a knee replacement designed just for them.

99. Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a medical device, and by said activities, caused the Zimmer Devices to be placed into the stream of commerce throughout the United States.

100. Zimmer actively marketed to doctors and the public that the Zimmer Devices were safe and effective total knee prosthesis.

101. The Zimmer NexGen Flex Knee, defined as including the Zimmer LPS-Flex, CR-Flex, LPS-Flex (GSF), CR-Flex (GSF) and/or MIS Tibial Components and any and all other Zimmer high-flexion knee systems and/or components predicated directly or indirectly upon the LPS-Flex Fixed Bearing Knee were aggressively marketed and promoted to the more active population, including Plaintiffs herein, promising state-of-art knee replacement providing greater flexion up to 155 degrees, and allowing for minimally invasive knee replacement.

102. Zimmer stated that the Flex Fixed Knee replacement was the first knee specifically designed to safely accommodate flexion of up to 155 degrees.

103. This information is part of a public awareness campaign by Zimmer, known as "Keeping pace with life," designed to educate patients about the Flex Fixed Knee as an option for total knee replacement.

104. The stated campaign goal is to provide patients with information and insight into the leading edge treatment for joint replacements to help them make educated decisions about their course of treatment.

105. In the US, Zimmer has aggressively marketed its high-flex versions as specifically designed for younger and more active total knee replacement patients “expecting to maintain an active lifestyle”.

106. In marketing materials touting its NexGen flex products, Zimmer explicitly acknowledged the lack of studies surrounding joint motion, yet unabashedly pushed to expand the market in the U.S. to literally create a need for its product.

107. Zimmer admitted that “in recent years, total knee arthroplasty (TKA) has brought about increasingly better, functional results and greater satisfaction to patients. Traditionally, 110 degrees to 115 degrees average passive flexion associated with TKA has been sufficient for Western patients. Western patients whose activities of daily living (ADL) involve chairs and beds may be content with a knee range of motion of 115 degrees.”

108. Nevertheless, Zimmer went on to say in trying to expand its market, Asian and Middle East patients may need greater flexion to adjust to the cultural demands of daily life where “normal range of motion...is considered to be between 130 degrees and 155 degrees.”

109. Zimmer then attempted to provide justification for expanding the market in the U.S. to provide the type of flexion required by Asian and Middle Eastern cultures: “There have been only a few studies published regarding the normal range of joint motion, and most of these are from the Western Hemisphere. As the reach of our designs

becomes more global, we know that there are many other cultural activities and lifestyles that require considerably more squatting and kneeling activities in everyday life.”

110. Without any self-restraint, Zimmer went on to create its flex market:

“the desire or need for flexion in excess of 115 degrees after TKA is not isolated to Asian and Middle East cultures only. There are Western patients that need the ability to achieve high flexion of the knee because of recreation and/or religious activities. Gardening is still a popular pastime and may require sitting on a low stool or kneeling. People of Roman Catholic faith often pray while kneeling, and the process of getting in and out of a kneeling position can be aided by high flexion capability.”

111. Zimmer’s approach to the aggressive - yet inadequately supported for safety or efficacy – campaign for the MIS Tibial device and procedure was no different.

112. A principle component of Zimmer’s marketing of the Zimmer Devices was the allure of the MIS surgical procedure, so much so that Zimmer went to the extensive effort to trademark the term “MIS” or “Minimally Invasive Solutions.”

113. Zimmer’s MIS Tibial components were marketed as “specifically designed to address the challenges and demands of minimally invasive TKA.” To achieve these goals, the design incorporated broad proximal fins that engage the tibia, while its low profile makes it easier to insert.

114. Zimmer’s promotional materials were specifically designed to induce physicians and patients that the use of the MIS Tibial components involved “MIS procedures are less invasive with smaller incisions, reduced blood loss, less pain and shorter hospital stays.”

115. By 2010, Zimmer was forced to admit that its marketing was false and that MIS procedures would not result in reduced risk. In April 2010, Zimmer sent an “Urgent Field Safety Notice”/“Urgent Device Correction” letter to all customers using the Zimmer NexGen MIS Tibial. With the urgent notice, gone were the claims of “less invasive” and “shorter hospital stays.” *Now* Zimmer admits that “MIS procedures are inherently challenging and can involve reduced visibility, which may lead to difficulty with achieving proper implant alignment and cement fixation.” On September 13, 2010, the FDA classified Zimmer’s efforts relating to the NexGen MIS Tibial components as a Class II Recall. About 68,384 MIS Tibial components contained defective surgical instructions and warnings.

116. Despite Zimmer’s marketing statements, its NexGen Knees identified herein provided little or no benefit as compared to traditional knee replacements, and began to fail in patients at alarming rates.

LACK OF EFFICACY AND FAILURE OF ZIMMER NEXGEN KNEES

117. There are several reasons for the failure of knee implants. The primary reason for failure implicated in this litigation is “mechanical loosening.” Mechanical “loosening” means that the attachment between the artificial knee and the existing bone has become loose.

118. Loosening can occur with any component of the artificial knee, including the femoral, tibial or patellar component.

119. Loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. Images of a loose knee joint are one or more radiolucent lines around the contours of the artificial knee joint.

120. A loose artificial knee causes pain and wearing away of the bone. A loose artificial knee can involve a severe physical burden for the patient and severely restrict the patient's daily activities.

121. Once the individual loses function of the knee or the pain becomes unbearable, another operation can be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

122. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

123. In an operation revising a total knee failure due to loosening, the most significant problem is often the reconstruction of the severe bone loss caused by the failed total knee prosthesis. The bone loss makes it difficult to restore the stability in the revised total knee.

124. The success rate of a revision operation is lower than that of the initial total knee replacement and the risks and complications are higher. The range of motion in the knee after revision surgery may decrease and the ability to walk may also be diminished. The rate of an artificial knee replacement loosening is higher after revision surgery than in primary knee replacement surgery.

125. There is a significant body of published literature as well as attention from the media and the United States Congress concerning greater than expected loosening and failure rates requiring revision surgery for the Zimmer Devices.

A. ***An Overview of the Problems Associated with NexGen Flex Knees***

1. ***The NexGen® High Flex Knees are Not Safe***

126. Throughout the past several years, there has been an increasing drum beat of evidence establishing that the so-called “High-Flex” knees: a) fail to provide additional or meaningful flexion beyond 120°; and b) fail at an artificially high rate when compared to their non-flex equivalents.

127. Starting in 2005, a study published in the Journal of Bone and Joint Surgery by Young-Hoo Kim entitled, Range of Motion of Standard and High-Flexion Posterior Stabilized Total Knee Prostheses, established no statistical significance between the degree of flexion in a group with a traditional LPS prosthesis versus a group with the LPS-Flex. Specifically, the authors reported that after two years, the mean range of motion/flexion in the LPS group versus the LPS-Flex group was a mere three degrees.

128. The *Kim* study was followed by a report in 2007 in The Journal of Bone and Joint Surgery (British Edition), published a peer reviewed study by professors at the Seoul National University College of Medicine entitled, High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilized-Flex Total Knee Replacement. The study showed that 38% of the implanted LPS high flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

129. In 2010 a new study by SD Cho published in the Knee Surgery, Sports Traumatology, Arthroscopy questioned the efficacy of high flex knees, specifically the LPS-flex. In the article, entitled, Three to six year follow-up results after high-flexion total knee arthroplasty: Can we allow passive deep knee bending?, the authors concluded that the LPS-flex knees were associated with a relatively high incidence of early loosening of the femoral components. Dr. Cho, the principle author of the study, stated

that squatting or kneeling may not even be permitted after implantation of the LPS-flex given these adverse effects.

130. In all, several peer reviewed studies have looked at the benefits of Zimmer's high-flex knees compared to standard knees and they repeatedly find that patients with the high-flex knees do not have better range of motion (ROM) than patients with the standard knees.

131. In fact, a recent study published in 2010 provided a meta-analysis of these studies, the majority of which involved NexGen knees. It reviewed and analyzed data from 11 studies comparing a total of 561 high-flex knees with 563 standard knee implants. Seven of the trials looked at Posterior Stabilized designs and four trials compared the Cruciate Retaining design implants. The analysis revealed that patients in each group, the high-flex and the standard, achieved an average post-operative ROM of 110 degrees. The analysis also revealed no statistical differences in knee ROM, weight-bearing flexion, knee scores and complications among the two groups.

132. Studies surrounding the NexGen Gender Solutions flex line have found similar lack of efficacy relating to the altered design which is claimed to provide a better fit for a female knee.

133. There have been several comparison studies looking at the outcomes of the Gender knee implants compared to their non-gender flex counter parts. A 2010 study involving 85 women who received the LPS-Flex in one knee and the Gender Solutions LPS-Flex in the other knee found no significant clinical benefits between the two groups. The mean range of motion was 125 degrees for the LPS-Flex and 126 for the gender specific LPS-Flex.

134. Another comparison study involving 138 women who received the CR-Flex in one knee and the Gender Solutions CR-Flex in the other, yielded the same results. The range of motion was 123 and 127 respectively for the two groups.

135. The scrutiny of Zimmer's failed high flex knees have not been limited to the peer reviewed medical literature.

136. On June 19, 2010 the *New York Times* unveiled an expose detailing a unacceptably high rate of failure rate for CR-Flex devices.

137. The *Times* article report on the findings of a former Zimmer consultant, Dr. Richard A. Berger.

138. Specifically, Berger raised concerns with Defendants regarding unacceptable failure rates of the CR-Flex. Berger, an orthopedic surgeon at Rush University Medical Center in Chicago, performed thousands of knee replacements almost exclusively using Zimmer products.

139. While a consultant for Zimmer, the company publicly praised Dr. Berger for his outstanding technique.

140. Ultimately, Berger along with a colleague at Rush University Medical Center, Dr. Craig Della Valle performed a study which they presented at the American Association of Orthopaedic Surgeons in March, 2010.

141. Specifically, Drs. Berger and Della Valle found that nearly ten percent of the devices they implanted failed and about half of the 100 patients studied showed signs of a-septic loosening. Rather than acknowledging the results, Zimmer instead responded to the findings by blaming Dr. Berger's surgical technique and disclaiming a defect in their product.

142. On July 29, 2010, US Senator Charles Grassley, disturbed by the *New York Times* story, sent a letter to Zimmer's President and CEO expressing concerns over the safety of the Zimmer NexGen Flex Knees in question. Senator Grassley directed Zimmer to address safety concerns, some of which included:

a. What process did Zimmer have in place to response to allegations and concerns raised by its consultants or contractors regarding the safety of one of its products?

b. How many consultants or contractors have raised safety concerns or problems regarding Zimmer's products?

c. What was the nature of the concerns

d. Did the concerns lead to safety modifications or product changes?

e. Of the safety concerns or problems identified since January 2008, how many were refuted by Zimmer?

f. Does Zimmer voluntarily collect data on the performance of its knee devices and other implantable devices?

g. If not, has Zimmer put in place a system to track the performance of these devices?

143. According to Senator Grassley's letter a response was requested by August 12, 2010. To date, Zimmer's response, if any, has not been made public. But the reports, serve as a major signal that thousands of individuals may have claims related to the failure of loosening of the Zimmer NexGen Knees.

2. *Zimmer has Manufactured and Distributed Thousands of Unsafe Knees*

144. Since 2003, Zimmer has manufactured and sold approximately 150,000 Zimmer NexGen High-Flex Knee implants.

145. From the time that Defendants first began selling the Zimmer NexGen High-Flex Knee the product labeling and product information for the Zimmer NexGen Flex Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen High-Flex Knee can loosen in patients.

146. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen High-Flex Knee, Defendants engaged in a marketing and advertising program which falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen Flex Knee was safe.

147. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen High-Flex Knee through promotional literature as well as sales visits to orthopedic surgeons, deceived doctors and potential users of the Zimmer NexGen Flex Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

B. MIS Tibial Components

148. The MIS tibial components were marketed as the first component to be designed for the MIS surgical procedures. It is generally used with NexGen CR/CR-Flex and NexGen LPS/LPS-Flex articular surfaces, as well as with the Gender Solutions

Female models to facilitate insertion through a smaller soft tissue window in which muscle and tendon cutting is minimized.

149. In March 2010, Dr. Steven Weeden, of the Texas Hip and Knee Center, presented at a national meeting of the American Association of Orthopedic Surgeons a study reporting a higher than expected rate of early loosening in cemented primary total knee replacements when a MIS Tibial component was used without an additional modular stem. In the MIS tibias components placed without an additional modular stem the failure rate was 24% versus 4.2% with a stem.

150. Notwithstanding the claims made by Zimmer regarding the MIS Tibial component, in or around April 2010, Defendants sent an “Urgent Field Safety Notice”/“Urgent Device Correction” letter to all customers using the MIS Tibial.

151. In that letter, Defendants acknowledged, in a stunning reversal of prior promotion and marketing of the MIS Tibial Component, that the prior procedures were wrong and potentially dangerous.

152. Specifically, whereas before Defendants marketed MIS procedures, including the MIS Tibial as “less invasive with smaller incisions, reduced blood loss, less pain and shorter hospital stays,” Defendants admitted that “*MIS procedures are inherently challenging and can involve reduced visibility*, which may lead to difficulty with achieving proper implant alignment and cement fixation.”

153. Defendants went on to alert physicians that “Required Actions” included “destroy or disregard all previous versions of the surgical technique [MIS].”

154. Finally, Defendants advised customers of a change in labeling and recommended usage of the MIS Tibial Component:

Zimmer is enhancing the labeling for the NexGen MIS Tibial Component in several important ways. The changes to the labeling include the following recommendations:

- a. To achieve adequate visualization and access if an MIS approach is used,
- b. To use a drop down stem extension with the NexGen MIS Tibial Component,
- c. To fully cement and pressurize the anterior and posterior surfaces of the tibial component, and
- d. To carefully use bone cement application per the manufacturer's instructions.

155. As of September 12, 2010, Zimmer had received complaints of loosening of the implanted device requiring revision surgery. There had been 114 MDRs (Medical Device Reports/complaints) filed; all reported that the device loosened and the patient required additional surgery to replace the device.

156. On September 13, 2010, the FDA classified the Defendants efforts relating to the MIS Tibial components as a Class II Recall.

157. From the time that Defendants first began selling the Zimmer NexGen MIS Tibia, the product labeling and product information for the Zimmer NexGen MIS Tibia failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen MIS Tibia can loosen in patients.

158. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen MIS Tibia, Defendants engaged in a marketing and advertising program

which falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen MIS Tibia was safe.

159. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen MIS Tibia through promotional literature as well as sales visits to orthopedic surgeons, deceived doctors and potential users of the Zimmer NexGen MIS Tibia by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FRAUDULENT CONCEALMENT AND DISCOVERY RULE

160. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

161. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants. Plaintiffs have been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

162. Plaintiffs could not reasonably have discovered the injury and its cause before the date of the revision surgery and/or the date of any recall notification to Plaintiffs and their doctors.

163. Defendants were under a continuing duty to disclose the true character, quality and nature of the Zimmer NexGen Family of devices identified herein, to the Plaintiffs. Because of their concealment of the true character, quality and nature of the Zimmer NexGen Family of devices to Plaintiffs, Defendants are stopped from relying on any statute of limitations defense.

**COUNT I (a) -- STRICT LIABILITY -- DESIGN DEFECT AS TO THE
ZIMMER LPS-FLEX**

164. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

165. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer LPS-Flex.

166. Defendants designed, manufactured, marketed, and sold the Zimmer LPS-Flex to medical professionals and their patients, knowing they would be implanted for knee replacements.

167. The Zimmer LPS-Flex was designed, manufactured, marketed and sold by Defendants, reached Plaintiffs without substantial change in its condition and were used by Plaintiffs in a reasonably foreseeable and intended manner.

168. The Zimmer LPS-Flex was “defective” and “unreasonably dangerous” when it entered the stream of commerce and was received by Plaintiffs, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

169. At no time did Plaintiffs have reason to believe that Zimmer LPS-Flex was in a condition not suitable for their proper and intended use among patients.

170. The Zimmer LPS-Flex was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiffs.

171. The Zimmer LPS-Flex was defective, due to defective design rendering the system unsafe.

172. The Zimmer LPS-Flex was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than

its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

173. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Zimmer LPS-Flex. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Zimmer LPS-Flex in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

174. The Zimmer LPS-Flex is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

175. The Zimmer LPS-Flex is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such as the LPS. The Zimmer LPS-Flex offers no clinical benefit over the traditional LPS knee or CR knee or the standard tibial component that compensates in whole or part for the increased risk.

176. The Zimmer LPS-Flex is unreasonably dangerous because it was sold to Plaintiffs without adequate warnings regarding, inter alia, the propensity of the Zimmer LPS-Flex to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer LPS-Flex; and the probability of suffering loosening and revision surgery.

177. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer LPS-Flex to Plaintiffs.

178. The Zimmer LPS-Flex is unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, inter alia, the increased risk of failure of Zimmer LPS-Flex resulting in revision surgery which is unreasonably greater than other knee implants such as the LPS and standard tibial. The high flexion knee devices offer no clinical benefits over the LPS knee, CR knee and /or standard tibial components that compensates in whole or part for the increased risk.

179. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer LPS-Flex.

180. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiffs and their physicians that Zimmer LPS-Flex causes serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

181. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer LPS-Flex, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

182. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT I (b) -- STRICT LIABILITY -- DESIGN DEFECT AS TO THE
ZIMMER CR-FLEX**

183. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

184. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer CR-Flex.

185. Defendants designed, manufactured, marketed, and sold the Zimmer CR-Flex to medical professionals and their patients, knowing they would be implanted for knee replacements.

186. The Zimmer CR-Flex was designed, manufactured, marketed and sold by Defendants, reached Plaintiffs without substantial change in its condition and were used by Plaintiffs in a reasonably foreseeable and intended manner.

187. The Zimmer CR-Flex was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiffs, because it was

dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

188. At no time did Plaintiffs have reason to believe that Zimmer CR-Flex is in a condition not suitable for their proper and intended use among patients.

189. The Zimmer CR-Flex was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiffs.

190. The Zimmer CR-Flex was defective, due to defective design rendering the system unsafe.

191. The Zimmer CR-Flex was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

192. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Zimmer CR-Flex. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Zimmer CR-Flex in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

193. The Zimmer CR-Flex is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

194. The Zimmer CR-Flex is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such

as the LPS. The Zimmer CR-Flex offers no clinical benefit over the traditional LPS knee or CR knee or the standard tibial component that compensates in whole or part for the increased risk.

195. The Zimmer CR-Flex is unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, *inter alia*, the propensity of the Zimmer CR-Flex to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer CR-Flex; and the probability of suffering loosening and revision surgery.

196. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer CR-Flex to Plaintiffs.

197. The Zimmer CR-Flex is unreasonably dangerous because it was sold to Plaintiffs without adequate warnings regarding, *inter alia*, the increased risk of failure of Zimmer CR-Flex resulting in revision surgery which is unreasonably greater than other knee implants such as the LPS and standard tibial. The high flexion knee devices offer no clinical benefits over the LPS knee, CR knee and /or standard tibial components that compensates in whole or part for the increased risk.

198. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer CR-Flex.

199. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiffs and their physicians that Zimmer CR-Flex causes serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

200. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer CR-Flex, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

201. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT I (c) -- STRICT LIABILITY -- DESIGN DEFECT AS TO THE
ZIMMER LPS-FLEX (GSF)**

202. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

203. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer LPS-Flex (GSF).

204. Defendants designed, manufactured, marketed, and sold the Zimmer LPS-Flex (GSF) to medical professionals and their patients, knowing they would be implanted for knee replacements.

205. The Zimmer LPS-Flex (GSF) was designed, manufactured, marketed and sold by Defendants, reached Plaintiffs without substantial change in its condition and were used by Plaintiffs in a reasonably foreseeable and intended manner.

206. The Zimmer LPS-Flex (GSF) was “defective” and “unreasonably dangerous” when it entered the stream of commerce and was received by Plaintiffs, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

207. At no time did Plaintiffs have reason to believe that Zimmer LPS-Flex (GSF) is in a condition not suitable for its proper and intended use among patients.

208. The Zimmer LPS-Flex (GSF) was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiffs.

209. The Zimmer LPS-Flex (GSF) was defective, due to defective design rendering the system unsafe.

210. The Zimmer LPS-Flex (GSF) was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

211. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Zimmer LPS-Flex

(GSF). Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Zimmer LPS-Flex (GSF) in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

212. The Zimmer LPS-Flex (GSF) is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

213. The Zimmer LPS-Flex (GSF) is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such as the LPS. The Zimmer LPS-Flex (GSF) offers no clinical benefit over the traditional LPS knee or CR knee or the standard tibial component that compensates in whole or part for the increased risk.

214. The Zimmer LPS-Flex (GSF) is unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, inter alia, the propensity of the Zimmer LPS-Flex (GSF) to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer LPS-Flex (GSF); and the probability of suffering loosening and revision surgery.

215. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer LPS-Flex (GSF) to Plaintiffs.

216. The Zimmer LPS-Flex (GSF) was unreasonably dangerous because it was sold to Plaintiffs without adequate warnings regarding, inter alia, the increased risk of failure of Zimmer LPS-Flex (GSF) resulting in revision surgery which is unreasonably

greater than other knee implants such as the LPS and standard tibial. The high flexion knee devices offer no clinical benefits over the LPS knee, CR knee and /or standard tibial components that compensates in whole or part for the increased risk.

217. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer LPS-Flex (GSF).

218. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiffs and their physicians that Zimmer LPS-Flex (GSF) causes serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

219. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer LPS-Flex (GSF), Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

220. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT I (d) -- STRICT LIABILITY -- DESIGN DEFECT AS TO THE
ZIMMER CR-FLEX (GSF)**

221. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

222. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer CR-Flex (GSF).

223. Defendants designed, manufactured, marketed, and sold the Zimmer CR-Flex (GSF) to medical professionals and their patients, knowing they would be implanted for knee replacements.

224. The Zimmer CR-Flex (GSF) was designed, manufactured, marketed and sold by Defendants, reached Plaintiffs without substantial change in its condition and were used by Plaintiffs in a reasonably foreseeable and intended manner.

225. The Zimmer CR-Flex (GSF) was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiffs, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

226. At no time did Plaintiffs have reason to believe that Zimmer CR-Flex (GSF) is in a condition not suitable for its proper and intended use among patients.

227. The Zimmer CR-Flex (GSF) was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiffs.

228. The Zimmer CR-Flex (GSF) was defective, due to defective design rendering the system unsafe.

229. The Zimmer CR-Flex (GSF) was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

230. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Zimmer CR-Flex (GSF). Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Zimmer CR-Flex (GSF) in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

231. The Zimmer CR-Flex (GSF) is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

232. The Zimmer CR-Flex (GSF) is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such as the LPS. The Zimmer CR-Flex (GSF) offers no clinical benefit over the traditional LPS knee or CR knee or the standard tibial component that compensates in whole or part for the increased risk.

233. The Zimmer CR-Flex (GSF) is unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, inter alia, the propensity of the Zimmer CR-Flex (GSF) to loosen and cause serious pain and necessitate additional

surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer CR-Flex (GSF); and the probability of suffering loosening and revision surgery.

234. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer CR-Flex (GSF) to Plaintiffs.

235. The Zimmer CR-Flex (GSF) is unreasonably dangerous because it was sold to Plaintiffs without adequate warnings regarding, inter alia, the increased risk of failure of Zimmer CR-Flex (GSF) resulting in revision surgery which is unreasonably greater than other knee implants such as the LPS and standard tibial. The high flexion knee devices offer no clinical benefits over the LPS knee, CR knee and /or standard tibial components that compensates in whole or part for the increased risk.

236. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer CR-Flex (GSF).

237. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiffs and their physicians that Zimmer CR-Flex (GSF) causes serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

238. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer CR-Flex (GSF), Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance,

immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

239. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT I (e) -- STRICT LIABILITY -- DESIGN DEFECT AS TO THE
ZIMMER MIS TIBIAL COMPONENTS**

240. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

241. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer MIS Tibial Components.

242. Defendants designed, manufactured, marketed, and sold the Zimmer MIS Tibial Components to medical professionals and their patients, knowing they would be implanted for knee replacements.

243. The Zimmer MIS Tibial Components are designed, manufactured, marketed and sold by Defendants, reached Plaintiffs without substantial change in their condition and were used by Plaintiffs in a reasonably foreseeable and intended manner.

244. The Zimmer MIS Tibial Components were “defective” and “unreasonably dangerous” when they entered the stream of commerce and were received by Plaintiffs, because they were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

245. At no time did Plaintiffs have reason to believe that Zimmer MIS Tibial Components are in a condition not suitable for its proper and intended use among patients.

246. The Zimmer MIS Tibial Components were used in the manner for which they were intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiffs.

247. The Zimmer MIS Tibial Components were defective, due to defective design rendering the system unsafe.

248. The Zimmer MIS Tibial Components were not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

249. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Zimmer MIS Tibial Components. Further, in no way could Plaintiffs have known that Defendants had designed, developed, and manufactured the Zimmer MIS Tibial Components in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

250. The Zimmer MIS Tibial Components are defective in design because of their propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

251. The Zimmer MIS Tibial Components are defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other tibial component surgery that is not minimally invasive or employs use of a drop down stem. The Zimmer MIS Tibial Components offer no clinical benefit over the non-minimally invasive surgery and/or surgery employing use of the tibial component with drop down stem that compensates in whole or part for the increased risk.

252. The Zimmer MIS Tibial Components are unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, inter alia, the propensity of the Zimmer MIS Tibial Components to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer MIS Tibial Components; and the probability of suffering loosening and revision surgery.

253. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer MIS Tibial Components to Plaintiffs.

254. The Zimmer MIS Tibial Components are unreasonably dangerous because they were sold to Plaintiffs without adequate warnings regarding, inter alia, the increased risk of failure of Zimmer MIS Tibial Components resulting in revision surgery which is unreasonably greater than other tibial component surgery that did not employ minimally

invasive surgery and/or employed use of a drop down stem that compensates in whole or part for the increased risk.

255. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer MIS Tibial Components.

256. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiffs and their physicians that Zimmer MIS Tibial Components cause serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

257. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer MIS Tibial Components, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

258. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II (a) -- STRICT LIABILITY -- FAILURE TO WARN AS TO THE ZIMMER LPS-FLEX

259. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further alleges as follows.

260. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer LPS-Flex, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer LPS-Flex.

261. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their prescribing physician, of the true risks of the Zimmer LPS-Flex, including that the Zimmer LPS-Flex could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

262. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer LPS-Flex. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiffs physicians, would have used the Zimmer LPS-Flex, or no consumer, including Plaintiffs, would have purchased and/or used the Zimmer LPS-Flex.

263. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer LPS-Flex. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer LPS-Flex, without causing serious pain and injury to patients, including Plaintiffs.

264. The Zimmer LPS-Flex, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer LPS-Flex and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer LPS-Flex.

265. The Zimmer LPS-Flex, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer LPS-Flex resulting in revision surgery while knowing that a safer alternative design including the traditional LPS knee, CR knee and standard tibial components existed.

266. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer LPS-Flex, even though they provide no clinical

benefits over other knee replacement systems such as the traditional LPS knee, CR knee and standard tibial components, and had a higher failure rate than the traditional LPS knee, CR knee and standard tibial components.

267. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

268. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs suffered serious and permanent non-economic and economic injuries.

269. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II (b) -- STRICT LIABILITY -- FAILURE TO WARN AS TO THE ZIMMER CR-FLEX

270. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further alleges as follows.

271. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer CR-Flex, in the course of same, directly advertised or

marketed the product to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer CR-Flex.

272. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their prescribing physician, of the true risks of the Zimmer CR-Flex, including that the Zimmer CR-Flex could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

273. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer CR-Flex. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiffs physicians, would have used the Zimmer CR-Flex, or no consumer, including Plaintiffs, would have purchased and/or used the Zimmer CR-Flex.

274. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer CR-Flex. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer CR-Flex, without causing serious pain and injury to patients, including Plaintiffs.

275. The Zimmer CR-Flex, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer

CR-Flex and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer CR-Flex.

276. The Zimmer CR-Flex, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer CR-Flex resulting in revision surgery while knowing that a safer alternative design including the traditional LPS knee, CR knee and standard tibial components existed.

277. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer CR-Flex, even though they provide no clinical benefits over other knee replacement systems such as the traditional LPS knee, CR knee and standard tibial components, and had a higher failure rate than the traditional LPS knee, CR knee and standard tibial components.

278. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

279. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs suffered serious and permanent non-economic and economic injuries.

280. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge

of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT II (c) -- STRICT LIABILITY -- FAILURE TO WARN AS TO THE
ZIMMER LPS-FLEX (GSF)**

281. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further alleges as follows.

282. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer LPS-Flex (GSF), in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer LPS-Flex (GSF).

283. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their prescribing physician, of the true risks of the Zimmer LPS-Flex (GSF), including that the Zimmer LPS-Flex (GSF) could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

284. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer LPS-Flex (GSF). Had they done so,

proper warnings would have been heeded and no health care professional, including Plaintiffs physicians, would have used the Zimmer LPS-Flex (GSF), or no consumer, including Plaintiffs, would have purchased and/or used the Zimmer LPS-Flex (GSF).

285. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer LPS-Flex (GSF). Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer LPS-Flex (GSF), without causing serious pain and injury to patients, including Plaintiffs.

286. The Zimmer LPS-Flex (GSF), which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer LPS-Flex (GSF) and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer LPS-Flex (GSF).

287. The Zimmer LPS-Flex (GSF), which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer LPS-Flex (GSF) resulting in revision surgery while knowing that a

safer alternative design including the traditional LPS knee, CR knee and standard tibial components existed.

288. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer LPS-Flex (GSF), even though they provide no clinical benefits over other knee replacement systems such as the traditional LPS knee, CR knee and standard tibial components, and had a higher failure rate than the traditional LPS knee, CR knee and standard tibial components.

289. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

290. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs suffered serious and permanent non-economic and economic injuries.

291. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT II (d) -- STRICT LIABILITY -- FAILURE TO WARN AS TO THE
ZIMMER CR-FLEX (GSF)**

292. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further alleges as follows.

293. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer CR-Flex (GSF), in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer CR-Flex (GSF).

294. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their prescribing physician, of the true risks of the Zimmer CR-Flex (GSF), including that the Zimmer CR-Flex (GSF) could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

295. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer CR-Flex (GSF). Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiffs physicians, would have used the Zimmer CR-Flex (GSF), or no consumer, including Plaintiffs, would have purchased and/or used the Zimmer CR-Flex (GSF).

296. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer CR-Flex (GSF). Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer CR-Flex (GSF), without causing serious pain and injury to patients, including Plaintiffs.

297. The Zimmer CR-Flex (GSF), which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer CR-Flex (GSF) and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer CR-Flex (GSF).

298. The Zimmer CR-Flex (GSF), which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer CR-Flex (GSF) resulting in revision surgery while knowing that a safer alternative design including the traditional LPS knee, CR knee and standard tibial components existed.

299. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer CR-Flex (GSF), even though they provide no clinical benefits over other knee replacement systems such as the traditional LPS knee, CR knee and standard tibial components, and had a higher failure rate than the traditional LPS knee, CR knee and standard tibial components.

300. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

301. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs suffered serious and permanent non-economic and economic injuries.

302. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT II (e) -- STRICT LIABILITY -- FAILURE TO WARN AS TO THE
ZIMMER MIS TIBIAL COMPONENTS**

303. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further alleges as follows.

304. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer MIS Tibial Components, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer MIS Tibial Components.

305. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their prescribing physician, of the true risks of the Zimmer MIS Tibial Components, including that the Zimmer MIS Tibial Components could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

306. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer MIS Tibial Components. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiffs physicians, would have used the Zimmer MIS Tibial Components, or no consumer, including Plaintiffs, would have purchased and/or used the Zimmer MIS Tibial Components.

307. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer MIS Tibial Components. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer MIS Tibial Components, without causing serious pain and injury to patients, including Plaintiffs.

308. The Zimmer MIS Tibial Components, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer MIS Tibial Components and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the

consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer MIS Tibial Components.

309. The MIS Tibial Components, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer MIS Tibial Components resulting in revision surgery while knowing that a safer alternative design including non-minimally invasive surgery and/or use of a drop down stem existed.

310. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiffs, and continued to aggressively promote the Zimmer MIS Tibial Components, even though they provide no clinical benefits over tibial component surgery that is non-minimally invasive and/or tibial components that have a drop down stem, and/or other standard tibial components, and had a higher failure rate than the traditional standard tibial components.

311. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

312. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiffs suffered serious and permanent non-economic and economic injuries.

313. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III (a) – STRICT LIABILITY – MANUFACTURING DEFECT AS TO THE ZIMMER LPS-FLEX

314. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

315. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer LPS-Flex, in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

316. The Zimmer LPS-Flex manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer LPS-Flex could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer LPS-Flex as a safe and effective knee replacement system.

317. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III (b) – STRICT LIABILITY – MANUFACTURING DEFECT AS TO THE ZIMMER CR-FLEX

318. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

319. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer CR-Flex, in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

320. The Zimmer CR-Flex manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer CR-Flex could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and

death from such further surgery, Defendants continued to market the Zimmer CR-Flex as a safe and effective knee replacement system.

321. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III (c) – STRICT LIABILITY – MANUFACTURING DEFECT AS TO THE ZIMMER LPS-FLEX (GSF)

322. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

323. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer LPS-Flex (GSF), in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

324. The Zimmer LPS-Flex (GSF) manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer LPS-Flex (GSF) could fail early in patients therefore giving rise to pain and

suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer LPS-Flex (GSF) as a safe and effective knee replacement system.

325. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III (d) – STRICT LIABILITY – MANUFACTURING DEFECT AS TO THE ZIMMER CR-FLEX (GSF)

326. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

327. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer CR-Flex (GSF), in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

328. The Zimmer CR-Flex (GSF) manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured

to the same design formula. Defendants knew or should have known that the Zimmer CR-Flex (GSF) could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer CR-Flex (GSF) as a safe and effective knee replacement system.

329. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III (e) – STRICT LIABILITY – MANUFACTURING DEFECT AS TO ZIMMER MIS TIBIAL COMPONENTS

330. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

331. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer MIS Tibial Components, in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

332. The Zimmer MIS Tibial Components manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants'

manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer MIS Tibial Components could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer MIS Tibial Components as a safe and effective knee replacement system.

333. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV (a) - NEGLIGENCE AS TO THE ZIMMER LPS-FLEX

334. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

335. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer LPS-Flex, including a duty to ensure that the Zimmer LPS-Flex did not pose a significantly increased risk of bodily injury to its users.

336. Defendants had a duty to exercise reasonable care in the advertising and

sale of the Zimmer LPS-Flex, including a duty to warn Plaintiffs and other consumers, of the dangers associated with the Zimmer LPS-Flex that were known or should have been known to Defendants at the time of the sale of the Zimmer LPS-Flex to the Plaintiffs.

337. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer LPS-Flex because Defendants knew or should have known that the Zimmer LPS-Flex had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

338. Defendants failed to exercise ordinary care in the labeling of the Zimmer LPS-Flex and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the risk of serious injury, including, loosening and revision surgery.

339. Defendants failed to exercise ordinary care in the labeling of the Zimmer LPS-Flex and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the increased risk of failure when compared to the comparable implants such as the traditional LPS knee, CR knee and standard tibial components while the Zimmer LPS-Flex offer no clinical benefits over the traditional LPS knee, CR knee and standard tibial components that compensates in whole or part for the increased risk.

340. Defendants knew or should have known that Plaintiffs could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

341. Defendants breached their duty of reasonable care to Plaintiffs by failing

to exercise due care under the circumstances as follows:

- a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer LPS-Flex, and/or to utilize and/or implement reasonably safe designs for them;
- b. Failing to provide adequate and proper warnings to the public and to Plaintiffs of the dangerous propensities of Zimmer LPS-Flex when used in a reasonably foreseeable manner;
- c. Failed to conduct adequate post marketing surveillance.
- d. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer LPS-Flex with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiffs when used in a reasonably foreseeable manner;
- e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer LPS-Flex in accordance with good design practices;
- f. Failing to notify and warn the public including Plaintiffs of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer LPS-Flex, thus misrepresenting the safety of the product;
- g. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer LPS-Flex so as to prevent and/or minimize the problems suffered by Zimmer LPS-Flex use;
- h. Failing to use due care in training and informing health care providers on

proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

i. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiffs' injuries having manifested themselves;

j. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,

k. Being otherwise being careless, reckless and negligent.

342. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer LPS-Flex and, Plaintiff(s) were implanted with the Zimmer LPS-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

343. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for

compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV (b) - NEGLIGENCE AS TO THE ZIMMER CR-FLEX

344. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

345. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer CR-Flex, including a duty to ensure that the Zimmer CR-Flex did not pose a significantly increased risk of bodily injury to its users.

346. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer CR-Flex, including a duty to warn Plaintiffs and other consumers, of the dangers associated with the Zimmer CR-Flex that were known or should have been known to Defendants at the time of the sale of the Zimmer CR-Flex to the Plaintiffs.

347. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer CR-Flex because Defendants knew or should have known that the Zimmer CR-Flex had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

348. Defendants failed to exercise ordinary care in the labeling of the Zimmer CR-Flex and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the risk of serious injury, including, loosening and revision surgery.

349. Defendants failed to exercise ordinary care in the labeling of the Zimmer

CR-Flex and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the increased risk of failure when compared to the comparable implants such as the traditional LPS knee, CR knee and standard tibial components while the Zimmer CR-Flex offer no clinical benefits over the traditional LPS knee, CR knee and standard tibial components that compensates in whole or part for the increased risk.

350. Defendants knew or should have known that Plaintiffs could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

351. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances as follows:

- a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer CR-Flex, and/or to utilize and/or implement reasonably safe designs for them;
- b. Failing to provide adequate and proper warnings to the public and to Plaintiffs of the dangerous propensities of Zimmer CR-Flex when used in a reasonably foreseeable manner;
- c. Failed to conduct adequate post marketing surveillance.
- d. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer CR-Flex with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiffs when used in a reasonably foreseeable manner;

e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer CR-Flex in accordance with good design practices;

f. Failing to notify and warn the public including Plaintiffs of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer CR-Flex, thus misrepresenting the safety of the product;

g. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer CR-Flex so as to prevent and/or minimize the problems suffered by Zimmer CR-Flex use;

h. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

i. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiffs' injuries having manifested themselves;

j. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,

k. Being otherwise being careless, reckless and negligent.

352. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer CR-Flex and, Plaintiff(s) were implanted with the Zimmer CR-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical

care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

353. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV (c) - NEGLIGENCE AS TO THE ZIMMER LPS-FLEX (GSF)

354. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

355. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer LPS-Flex, (GSF) including a duty to ensure that the Zimmer LPS-Flex (GSF) did not pose a significantly increased risk of bodily injury to its users.

356. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer LPS-Flex (GSF), including a duty to warn Plaintiffs and other consumers, of the dangers associated with the Zimmer LPS-Flex (GSF) that were known

or should have been known to Defendants at the time of the sale of the Zimmer LPS-Flex (GSF) to the Plaintiffs.

357. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer LPS-Flex (GSF) because Defendants knew or should have known that the Zimmer LPS-Flex (GSF) had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

358. Defendants failed to exercise ordinary care in the labeling of the Zimmer LPS-Flex (GSF) and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the risk of serious injury, including, loosening and revision surgery.

359. Defendants failed to exercise ordinary care in the labeling of the Zimmer LPS-Flex (GSF) and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the increased risk of failure when compared to the comparable implants such as the traditional LPS knee, CR knee and standard tibial components while the Zimmer LPS-Flex (GSF) offer no clinical benefits over the traditional LPS knee, CR knee and standard tibial components that compensates in whole or part for the increased risk.

360. Defendants knew or should have known that Plaintiffs could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

361. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer LPS-Flex (GSF), and/or to utilize and/or implement reasonably safe designs for them;

b. Failing to provide adequate and proper warnings to the public and to Plaintiffs of the dangerous propensities of Zimmer LPS-Flex (GSF) when used in a reasonably foreseeable manner;

c. Failed to conduct adequate post marketing surveillance.

d. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer LPS-Flex (GSF) with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiffs when used in a reasonably foreseeable manner;

e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer LPS-Flex (GSF) in accordance with good design practices;

f. Failing to notify and warn the public including Plaintiffs of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer LPS-Flex (GSF), thus misrepresenting the safety of the product;

g. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer LPS-Flex (GSF) so as to prevent and/or minimize the problems suffered by Zimmer LPS-Flex (GSF) use;

h. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

i. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiffs' injuries having manifested themselves;

j. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,

k. Being otherwise being careless, reckless and negligent.

362. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer LPS-Flex (GSF) and, Plaintiff(s) were implanted with the Zimmer LPS-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

363. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV (d) - NEGLIGENCE AS TO THE ZIMMER CR-FLEX (GSF)

364. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

365. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer CR-Flex (GSF), including a duty to ensure that the Zimmer CR-Flex (GSF) did not pose a significantly increased risk of bodily injury to its users.

366. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer CR-Flex (GSF), including a duty to warn Plaintiffs and other consumers, of the dangers associated with the Zimmer CR-Flex (GSF) that were known or should have been known to Defendants at the time of the sale of the Zimmer CR-Flex (GSF) to the Plaintiffs.

367. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer CR-Flex (GSF) because Defendants knew or should have known that the Zimmer CR-Flex (GSF) had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

368. Defendants failed to exercise ordinary care in the labeling of the Zimmer

CR-Flex (GSF) and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the risk of serious injury, including, loosening and revision surgery.

369. Defendants failed to exercise ordinary care in the labeling of the Zimmer CR-Flex (GSF) and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the increased risk of failure when compared to the comparable implants such as the traditional LPS knee, CR knee and standard tibial components while the Zimmer CR-Flex (GSF) offer no clinical benefits over the traditional LPS knee, CR knee and standard tibial components that compensates in whole or part for the increased risk.

370. Defendants knew or should have known that Plaintiffs could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

371. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances as follows:

- a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer CR-Flex (GSF), and/or to utilize and/or implement reasonably safe designs for them;
- b. Failing to provide adequate and proper warnings to the public and to Plaintiffs of the dangerous propensities of Zimmer CR-Flex (GSF) when used in a reasonably foreseeable manner;
- c. Failed to conduct adequate post marketing surveillance.

- d. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer CR-Flex (GSF) with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiffs when used in a reasonably foreseeable manner;
 - e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer CR-Flex (GSF) in accordance with good design practices;
 - f. Failing to notify and warn the public including Plaintiffs of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer CR-Flex (GSF), thus misrepresenting the safety of the product;
 - g. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer CR-Flex (GSF) so as to prevent and/or minimize the problems suffered by Zimmer CR-Flex (GSF) use;
 - h. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;
 - i. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiffs' injuries having manifested themselves;
 - j. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,
 - k. Being otherwise being careless, reckless and negligent.
372. As a direct and proximate result of Defendants' acts and omissions,

including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer CR-Flex (GSF) and, Plaintiff(s) were implanted with the Zimmer CR-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

373. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV (e) - NEGLIGENCE AS TO THE ZIMMER MIS TIBIAL COMPONENTS

374. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

375. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer MIS Tibial Components, including a duty to ensure that the Zimmer MIS Tibial Components did not pose a significantly increased risk of bodily injury to its users.

376. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer MIS Tibial Components, including a duty to warn Plaintiffs and other consumers, of the dangers associated with the Zimmer MIS Tibial Components that were known or should have been known to Defendants at the time of the sale of the Zimmer MIS Tibial Components to the Plaintiffs.

377. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer MIS Tibial Components because Defendants knew or should have known that the Zimmer MIS Tibial Components had a propensity to cause serious injury, including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

378. Defendants failed to exercise ordinary care in the labeling of the Zimmer MIS Tibial Components and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the risk of serious injury, including, loosening and revision surgery.

379. Defendants failed to exercise ordinary care in the labeling of the Zimmer MIS Tibial Components and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiffs, regarding the increased risk of failure when compared to comparable surgery that did not employ minimally invasive procedure and/or when compared to comparable surgery that was minimally invasive but used a drop down stem and/or other standard tibial components since the Zimmer MIS Tibial Components offer no clinical benefits that compensate in whole or part for the increased risk.

380. Defendants knew or should have known that Plaintiffs could foreseeably

suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

381. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer MIS Tibial Components, and/or to utilize and/or implement reasonably safe designs for them;

b. Failing to provide adequate and proper warnings to the public and to Plaintiffs of the dangerous propensities of Zimmer MIS Tibial Components when used in a reasonably foreseeable manner;

c. Failed to conduct adequate post marketing surveillance.

d. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer MIS Tibial Components with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiffs when used in a reasonably foreseeable manner;

e. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer MIS Tibial Components in accordance with good design practices;

f. Failing to notify and warn the public including Plaintiffs of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer MIS Tibial Components, thus misrepresenting the safety of the product;

g. Failing to make timely and adequate corrections to the manufacture,

design and formulation of Zimmer MIS Tibial Components so as to prevent and/or minimize the problems suffered by Zimmer MIS Tibial Components use;

h. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;

i. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiffs' injuries having manifested themselves;

j. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,

k. Being otherwise being careless, reckless and negligent.

382. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer MIS Tibial Components and, Plaintiff(s) were implanted with the Zimmer MIS Tibial Components and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

383. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT V (a) - NEGLIGENT MISREPRESENTATION AS TO THE
ZIMMER LPS-FLEX**

384. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

385. Prior to the Plaintiffs receiving the Zimmer LPS-Flex, Defendants misrepresented that the Zimmer LPS-Flex were a safe and effective total knee replacement system.

386. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer LPS-Flex, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS knee, CR knee and standard tibial components.

387. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

388. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer LPS-Flex that their representations regarding Zimmer LPS-

Flex were false, and that they had a duty to disclose the dangers associated with the device.

389. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by purchasing the Zimmer LPS-Flex.

390. Plaintiffs and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer LPS-Flex.

391. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer LPS-Flex was the direct and proximate cause of Plaintiff's injuries.

392. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT V (b) - NEGLIGENT MISREPRESENTATION AS TO THE
ZIMMER CR-FLEX**

393. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

394. Prior to the Plaintiffs receiving the Zimmer CR-Flex, Defendants misrepresented that the Zimmer CR-Flex were a safe and effective total knee replacement system.

395. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer CR-Flex, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS knee, CR knee and standard tibial components.

396. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

397. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer CR-Flex that their representations regarding Zimmer CR-Flex were false, and that they had a duty to disclose the dangers associated with the device.

398. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by purchasing the Zimmer CR-Flex.

399. Plaintiffs and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer CR-Flex.

400. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer CR-Flex was the direct and proximate cause of Plaintiff's injuries.

401. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT V (c) - NEGLIGENT MISREPRESENTATION AS TO THE
ZIMMER LPS-FLEX (GSF)**

402. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

403. Prior to the Plaintiffs receiving the Zimmer LPS-Flex (GSF), Defendants misrepresented that the Zimmer LPS-Flex (GSF) were a safe and effective total knee replacement system.

404. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer LPS-Flex (GSF), including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS knee, CR knee and standard tibial components.

405. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

406. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer LPS-Flex (GSF) that their representations regarding Zimmer LPS-Flex (GSF) were false, and that they had a duty to disclose the dangers associated with the device.

407. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by purchasing the Zimmer LPS-Flex (GSF).

408. Plaintiffs and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer LPS-Flex (GSF).

409. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer LPS-Flex (GSF) was the direct and proximate cause of Plaintiff's injuries.

410. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT V (d) - NEGLIGENT MISREPRESENTATION AS TO THE
ZIMMER CR-FLEX (GSF)**

411. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

412. Prior to the Plaintiffs receiving the Zimmer CR-Flex (GSF), Defendants misrepresented that the Zimmer CR-Flex (GSF) were a safe and effective total knee replacement system.

413. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer CR-Flex (GSF), including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS knee, CR knee and standard tibial components.

414. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

415. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer CR-Flex (GSF) that their representations regarding Zimmer CR-Flex (GSF) were false, and that they had a duty to disclose the dangers associated with the device.

416. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by purchasing the Zimmer CR-Flex (GSF).

417. Plaintiffs and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer CR-Flex (GSF).

418. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer CR-Flex (GSF) was the direct and proximate cause of Plaintiff's injuries.

419. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT V (e) - NEGLIGENT MISREPRESENTATION AS TO THE
ZIMMER MIS TIBIAL COMPONENTS**

420. Plaintiffs incorporate by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

421. Prior to the Plaintiffs receiving the Zimmer MIS Tibial Components, Defendants misrepresented that the Zimmer MIS Tibial Components were part of a safe and effective total knee replacement system.

422. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer MIS Tibial Components, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of studies and or data known or knowable to Defendants showing an increased risk of revision with little to no clinical benefit over comparable surgery that did not use minimally invasive procedure and/or employed use of a drop down stem.

423. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

424. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer MIS Tibial Components that their representations regarding Zimmer MIS Tibial Components were false, and that they had a duty to disclose the dangers associated with the device.

425. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by purchasing the Zimmer MIS Tibial Components.

426. Plaintiffs and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer MIS Tibial Components.

427. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer MIS Tibial Components was the direct and proximate cause of Plaintiff's injuries.

428. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VI (a) - BREACH OF EXPRESS WARRANTY AS TO THE
ZIMMER LPS-FLEX**

429. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

430. Defendants advertised, labeled, marketed and promoted the Zimmer LPS-Flex, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer LPS-Flex would conform to the representations. More specifically, Defendants represented that the Zimmer LPS-Flex was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

431. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

432. The Zimmer LPS-Flex did not conform to the representations made by Defendants in that the Zimmer LPS-Flex was not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat in individuals, such as Plaintiffs.

433. At all relevant times, Plaintiffs used the Zimmer LPS-Flex for the purpose and in the manner intended by Defendants.

434. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

435. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

436. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer LPS-Flex and, Plaintiffs were implanted with Zimmer LPS-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VI (b) - BREACH OF EXPRESS WARRANTY AS TO THE
ZIMMER CR-FLEX**

437. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

438. Defendants advertised, labeled, marketed and promoted the Zimmer CR-Flex, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer CR-Flex would conform to the representations. More specifically, Defendants represented that the Zimmer CR-Flex was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

439. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

440. The Zimmer CR-Flex did not conform to the representations made by Defendants in that the Zimmer CR-Flex was not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat in individuals, such as Plaintiffs.

441. At all relevant times, Plaintiffs used the Zimmer CR-Flex for the purpose and in the manner intended by Defendants.

442. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

443. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

444. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer CR-Flex and, Plaintiffs were implanted with Zimmer CR-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VI (c) - BREACH OF EXPRESS WARRANTY AS TO THE
ZIMMER LPS-FLEX (GSF)**

445. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

446. Defendants advertised, labeled, marketed and promoted the Zimmer LPS-Flex (GSF), representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer LPS-Flex (GSF) would conform to the representations. More specifically, Defendants represented that the Zimmer LPS-Flex (GSF) was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

447. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the

goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

448. The Zimmer LPS-Flex (GSF) did not conform to the representations made by Defendants in that the Zimmer LPS-Flex (GSF) was not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat in individuals, such as Plaintiffs.

449. At all relevant times, Plaintiffs used the Zimmer LPS-Flex (GSF) for the purpose and in the manner intended by Defendants.

450. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

451. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

452. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer LPS-Flex (GSF) and, Plaintiffs were implanted with Zimmer LPS-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VI (d) - BREACH OF EXPRESS WARRANTY AS TO THE
ZIMMER CR-FLEX (GSF)**

453. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

454. Defendants advertised, labeled, marketed and promoted the Zimmer CR-Flex (GSF), representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer CR-Flex (GSF) would conform to the representations. More specifically, Defendants represented that the Zimmer CR-Flex (GSF) was safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

455. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

456. The Zimmer CR-Flex (GSF) did not conform to the representations made by Defendants in that the Zimmer CR-Flex (GSF) was not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat in individuals, such as Plaintiffs.

457. At all relevant times, Plaintiffs used the Zimmer CR-Flex (GSF) for the purpose and in the manner intended by Defendants.

458. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

459. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

460. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer CR-Flex (GSF) and, Plaintiffs were implanted with Zimmer CR-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VI (e) - BREACH OF EXPRESS WARRANTY AS TO THE
ZIMMER MIS TIBIAL COMPONENTS**

461. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

462. Defendants advertised, labeled, marketed and promoted the Zimmer MIS Tibial Components, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer MIS Tibial Components would conform to the representations. More specifically, Defendants represented that the Zimmer MIS Tibial Components were safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective to treat Plaintiffs' condition.

463. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

464. The Zimmer MIS Tibial Components did not conform to the representations made by Defendants in that the Zimmer MIS Tibial Components were not safe and effective, was not safe and effective for use by individuals such as Plaintiffs, and/or was not safe and effective to treat in individuals, such as Plaintiffs.

465. At all relevant times, Plaintiffs used the Zimmer MIS Tibial Components for the purpose and in the manner intended by Defendants.

466. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

467. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

468. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer MIS Tibial Components and, Plaintiffs were implanted with Zimmer MIS Tibial Components and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VII (a) - BREACH OF IMPLIED WARRANTIES AS TO THE
ZIMMER LPS-FLEX**

469. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

470. The Zimmer LPS-Flex was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer LPS-Flex minimally safe for its expected purpose.

471. At all relevant times, Plaintiffs used the Zimmer LPS-Flex for the purpose and in the manner intended by Defendants.

472. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

473. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

474. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer LPS-Flex, Plaintiffs were implanted with Zimmer LPS-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which

they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VII (b) - BREACH OF IMPLIED WARRANTIES AS TO THE
ZIMMER CR-FLEX**

475. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

476. The Zimmer CR-Flex was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer CR-Flex minimally safe for its expected purpose.

477. At all relevant times, Plaintiffs used the Zimmer CR-Flex for the purpose and in the manner intended by Defendants.

478. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

479. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

480. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer CR-Flex, Plaintiffs were implanted with Zimmer CR-Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income,

permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VII (c) - BREACH OF IMPLIED WARRANTIES AS TO THE
ZIMMER LPS-FLEX (GSF)**

481. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

482. The Zimmer LPS-Flex (GSF) was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer LPS-Flex (GSF) minimally safe for its expected purpose.

483. At all relevant times, Plaintiffs used the Zimmer LPS-Flex (GSF) for the purpose and in the manner intended by Defendants.

484. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

485. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

486. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer LPS-Flex (GSF), Plaintiffs were implanted

with Zimmer LPS-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VII (d) - BREACH OF IMPLIED WARRANTIES AS TO THE
ZIMMER CR-FLEX (GSF)**

487. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

488. The Zimmer CR-Flex (GSF) was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer CR-Flex (GSF) minimally safe for its expected purpose.

489. At all relevant times, Plaintiffs used the Zimmer CR-Flex (GSF) for the purpose and in the manner intended by Defendants.

490. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

491. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

492. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer CR-Flex (GSF), Plaintiffs were implanted with Zimmer CR-Flex (GSF) and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VII (e) - BREACH OF IMPLIED WARRANTIES AS TO THE
ZIMMER MIS TIBIAL COMPONENTS**

493. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

494. The Zimmer MIS Tibial Components were not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were the Zimmer MIS Tibial Components minimally safe for its expected purpose.

495. At all relevant times, Plaintiffs used the Zimmer MIS Tibial Components for the purpose and in the manner intended by Defendants.

496. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

497. The breach of the warranty was a substantial factor in bringing about Plaintiffs injuries.

498. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer MIS Tibial Components, Plaintiffs were implanted with Zimmer MIS Tibial Components and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII (a) – REDHIBITION AS TO THE ZIMMER LPS-FLEX

499. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

500. The Zimmer LPS-Flex contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have had the Zimmer LPS-Flex implanted.

501. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described

above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have had the Zimmer LPS-Flex implanted had he known of the defects. The Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

502. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have purchased it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

503. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, Defendant is deemed to know that the subject product possessed a redhibitory defect.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII (b) – REDHIBITION AS TO THE ZIMMER CR-FLEX

504. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

505. The Zimmer CR-Flex contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have had the Zimmer CR-Flex implanted.

506. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have had the Zimmer CR-Flex implanted had he known of the defects. The Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

507. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have purchased it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

508. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, Defendant is deemed to know that the subject product possessed a redhibitory defect.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII (c) – REDHIBITION AS TO THE ZIMMER LPS-FLEX

(GSF)

509. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

510. The Zimmer LPS-Flex (GSF) contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have had the Zimmer LPS-Flex (GSF) implanted.

511. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have had the Zimmer LPS-Flex (GSF) implanted had he known of the defects. The Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

512. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have

purchased it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

513. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, Defendant is deemed to know that the subject product possessed a redhibitory defect.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII (d) – REDHIBITION AS TO THE ZIMMER CR-FLEX (GSF)

514. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

515. The Zimmer CR-Flex (GSF) contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have had the Zimmer CR-Flex (GSF) implanted.

516. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be

presumed that a buyer would not have had the Zimmer CR-Flex (GSF) implanted had he known of the defects. The Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

517. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have purchased it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

518. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, Defendant is deemed to know that the subject product possessed a redhibitory defect.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII (e) – REDHIBITION AS TO THE ZIMMER MIS TIBIAL COMPONENTS

519. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

520. The Zimmer MIS Tibial Components contain a vice or defect which renders it useless or its use so inconvenient that buyers would not have had the Zimmer MIS Tibial Components implanted.

521. Defendants sold and promoted the subject product, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The subject product sold and promoted by the Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have had the Zimmer MIS Tibial Components implanted had he known of the defects. The Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

522. The subject product alternatively possess a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have purchased it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

523. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect and thus are liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject

COUNT IX – LOSS OF CONSORTIUM

525. At all times relevant hereto the Plaintiffs spouses (hereinafter referred to as “Spouse Plaintiffs”) and/or family members (hereinafter referred to as “Family Member Plaintiffs”) who have suffered injuries and losses as a result of Plaintiffs’ injuries.

527. For the reason set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love, and affection.

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529. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

530. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X – WRONGFUL DEATH

531. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

532. Decedent Plaintiffs died as a result of defects in Defendants' subject product and are survived by various family members, named and unnamed.

533. The representatives/administrators of Decedent Plaintiffs' estate bring this claim on behalf of the Decedent Plaintiffs' lawful heirs.

534. Defendants' wrongful conduct has proximately caused Decedents Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love, consortium and all other damages allowed under state statutes and laws.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

537. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

539. The representatives/administrator of Decedent Plaintiffs' estate bring this claim on behalf of Decedent Plaintiffs' estate and Decedents Plaintiffs' beneficiaries for damages.

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WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII

(Violation of Consumer Protection Statutes)

541. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

542. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when it failed to adequately warn consumers and the medical community of the safety risks associated with the Zimmer Devices. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

543. This Master Long Form Complaint Plaintiffs has been filed in accordance with Order of this Court. Accordingly, there are no "party plaintiffs" to this document. However to the extent an individual by his or her attorney enter a pleading by way of adoption then it is alleged that Plaintiff is a resident of the state set forth in the pleading by way of adoption and wherever a given plaintiff resides, then that state's consumer protection law violation will be adopted by reference.

544. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471.

545. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. Ann. §§44-1521 *et seq.*

546. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. §§4-8-101 *et seq.*

547. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §§1770 *et seq.* and Cal. Bus. & Prof. Code §§ 17200 *et seq.*

548. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §§6-1-105 *et seq.*

549. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. Ann. §§42-110a *et seq.*

550. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6 §§2511 *et seq.* and 2531 *et seq.*

551. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of D.C. Code Ann. §§28-3901 *et seq.*

552. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Stat. Ann. §501.201.

553. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §§10-1-372 and 10-1-420.

554. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §§480-1 *et seq.*

555. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code §§48-601 *et seq.*

556. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Ill. Comp. Stat. 505/1 *et seq.*

557. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. 24-5-0.5-3.

558. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.16.

559. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. Ann. §§50-623 *et seq.*

560. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. Ann. §367.170.

561. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Me. Rev. Sta. Ann. tit. 5, §§205-A *et seq.*

562. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Code Ann., Com. Law §§13-301 *et seq.*

563. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ge. Laws ch. 93A, §§I *et seq.*

564. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. §§445.901 *et seq.*

565. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Ann. Stat. §§407.010 *et seq.*

566. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Aim. §§30-14-101 *et seq.*

567. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §§59-1601 *et seq.*

568. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. §§598.0903 *et seq.*

569. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. Ann. §§358-A:1 *et seq.*

570. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. §§56:8-1 *et seq.*

571. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §§57-12-1 *et seq.*

572. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§349 *et seq.* and 350-e *et seq.*

573. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §§75-1 *et seq.*

574. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§51-12-01 *et seq.* and 51-15-01 *et seq.*

575. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Code Ann. §§1345.01 *et seq.*

576. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representation in violation of Okla. Stat. Ann. tit. 15, §§751 *et seq.*

577. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. §§646.605 *et seq.*

578. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Cons. Stat. §§201-1 *et seq.*

579. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§6-13.1-1 *et seq.*

580. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Ann. §§39-5-10 *et seq.*

581. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§37-24-1 *et seq.*

582. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. §47-18-109(a)(l).

583. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 *et seq.*

584. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §§13-11-1 *et seq.*

585. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §§2453 *et seq.*

586. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. §§59.1-196 *et seq.*

587. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code Ann. §§19.86.010 *et seq.*

588. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W.Va. Code 46A-6-101 *et seq.*

589. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. Ann. §100.18.

590. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. Ann. §§40-12-101 *et seq.*

591. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. State. §325D.44(13) *et. seq.* and Minn. Stat. § 325F.67

592. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of the Zimmer Devices and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material

facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

593. The medical community relied upon Defendants' misrepresentations and omissions in determining which knee device to utilize.

594. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

595. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

COUNT XIII-UNJUST ENRICHMENT

596. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

597. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiff made for the Zimmer Devices and from payments Plaintiff has made for replacement for the Zimmer Device.

598. In exchange for the payments made for the Zimmer Devices, and at the time payments were made, Plaintiff expected that the Zimmer Devices were safe and medically effective treatment for the condition, illness, disorder, or symptom for which they were prescribed.

599. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff paid

for the Zimmer Device and were forced to pay for a replacement device when they otherwise would not have done so. The failure of Defendants to provide Plaintiff with the remuneration expected enriched Defendants unjustly.

600. Plaintiff is entitled in equity to seek restitution of Defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT XIV – PUNITIVE DAMAGES

600. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

601. At all times material hereto, the Defendant knew or should have known that Zimmer LPS-Flex, CR-Flex, LPS-Flex (GSF), CR-Flex (GSF) and/or MIS Tibial Components and any and all other Zimmer high-flexion knee systems and/or components predicated directly or indirectly upon the LPS-Flex Fixed Bearing Knee were inherently more dangerous with respect to the risk of loosening and a shorter life span and need for additional surgeries than the alternative knee replacement systems on the market.

602. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

603. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

604. At all times material hereto, the Defendant knew and recklessly disregarded the fact that the Zimmer NexGen Flex Knees was subject to loosening in

persons implanted with the device with far greater frequency than safer alternative knee replacement systems.

605. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

606. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm.

607. The Defendants intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiffs and their surgeons of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

608. As a direct and proximate result of the Defendants conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiffs, the Plaintiffs suffered severe and permanent physical injuries as set forth above.

609. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiffs, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

610. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief against Defendants, jointly and severally, as follows:

- a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiffs for all their injuries and damages, both past and present;
- b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.
- c. Double or triple damages as allowed by law;
- d. Attorneys' fees, expenses, and costs of this action;
- e. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- f. Punitive damages
- f. Such further relief as this Court deems necessary, just, and proper.

Dated: January 12, 2012

Respectfully submitted,
POGUST BRASLOW & MILLROOD, LLC

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Proposed Plaintiffs' Liaison Counsel

CERTIFICATE OF SERVICE

I certify that on January 12, 2012, a copy of the foregoing *Master Long Form Complaint* was filed electronically by using the CM/ECF system, which will deliver the document to all counsel of record.

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